

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 43-63 are pending in the application. Support for claims 43-63 may be found generally throughout the specification and in the original claims. In particular the Examiner's attention is respectfully directed to page 4, line 1 to page 5, line 18 as support for claims 43-63. Claims 1-42 have been canceled.

In the outstanding Official Action, claims 22-34 were rejected under 35 USC 112, first paragraph, for allegedly not satisfying the written description requirement. This rejection is respectfully traversed.

Applicants understand that the Patent Office interprets the term "prevention" as an absolute (i.e., the recited condition never occurs again). Applicants have amended the claims so that the term "prevention" is no longer recited. However, applicants do not disclaim any potential applications or uses for the claimed methods or compositions (e.g., treating a person prospectively). As the term "prevention" is no longer recited in the claims, applicants respectfully request that this rejection be withdrawn.

Claims 22-34 and 40 were rejected under 35 USC 112, second paragraph, for allegedly being indefinite.

As noted above, claims 1-42 have been canceled. Applicants believe that new claims 43-65 have been drafted in a non-narrowing manner so as to avoid the issues raised in the indefiniteness rejection. Indeed, the claims have been drafted so as to avoid the phrases "a method of treatment and/or prevention of hyperglycaemic syndromes and in particular of treatment of type 2 diabetes", "in appropriate amount", "such as", "disaccharides (maltose, luucolse, sacharose", and "trisaccharides (panose, maltotriose)".

Thus, in view of the above, applicants respectfully request that this rejection be withdrawn.

Claims 29 and 32-34 were rejected under 35 USC 102(b) as allegedly being anticipated by MIYAKI et al. This rejection is traversed.

MIYAKI et al. is directed to a process for producing orally-usable products possessing low- or anti-cariogenic properties. The process comprises preparing the products with a saccharide having a substantial anti-cariogenicity. The saccharide may be isomaltosyl mono-, di-, tri-glucoses, and reduction products thereof (e.g., panose, isomaltotriose, isomaltosyl maltose, isomaltotetraose, isomaltopentaose, and reduction products thereof) (col. 18, lines 12-30). Thus, MIYAKI et al discloses a food composition substantially comprising isomaltriose, isomaltotetraose, and isomaltopentose.

MIYAKI et al. do not disclose or suggest a method for treating hyperglycaemic syndrome and/or diabetes in a subject. Accordingly, MIYAKI et al. do not anticipate method claims 43-50.

As to compositions claims 51-63, applicants respectfully submit that the composition claims have been drafted so as to exclude the composition disclosed by MIYAKI et al (e.g., see independent claims 51 and 54). The Examiner's attention is also respectfully directed to claim 63, which recites a composition with a number of ingredients and amounts not recited by MIYAKI et al.

As the Examiner is aware, a claim is anticipated only if each and every recitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). As MIYAKI et al. do not disclose or suggest each and every recitation, applicants submit that MIYAKI et al. fail to anticipate the claimed invention.

Claims 35, 41 and 42 were rejected under 35 USC 102(b) as allegedly being anticipated by LETTELIER et al. This rejection is traversed.

LETTELIER disclose composition for inhibiting *Salmonella* in pigs. Accordingly, applicants respectfully submit that LETTELIER fails to disclose or suggest any of the pending method claims.

As to the composition claims, LETTELIER disclose a composition comprising fructooligosaccharides. However, applicants respectfully submit that independent claims 51 and 54 have been drafted to exclude the LETTELIER composition comprising the fructooligosaccharides as recited in LETTELIER. Claim 63 recites a composition with a number of ingredients and amounts not suggested by LETTELIER. As LETTELIER does not disclose or suggest each and every recitation, applicants submit that LETTELIER fails to anticipate claim 63.

Claims 22, 25, 28-32, 35-38, 41 and 42 were rejected under 35 USC 103(a) as allegedly being unpatentable over ROBERFROID et al. This rejection is traversed.

Contrary to the assertions of the Official Action, ROBERFROID et al. do not suggest that the food composition described in Fig. 1 (p. 119) could be used to treat diabetes and obesity. Rather, ROBERFROID et al.'s food composition is known and commonly used in the food industry for the conversion of inulin into ethanol as in the production of alcoholic drink (such as tequila from agave, p. 119) or for the production of synthetic fructans (p. 120).

Therefore, one skilled person would have lacked the motivation and a reasonable expectation of success to utilize the composition in a method for treating hyperglycemic syndrome and/or type II diabetes in a subject as recited in the claimed invention (see independent claim 43).

Moreover, at page 129, ROBERFROID et al. note the "contradictory" effects of these fructans on glycemia and insulinemia, emphasizing "that these effect may depend on physiological (fasting versus postprandial state) or disease (diabetes) conditions." In this regard, ROBERFROID et al. also state, "the glycemic response during a glucosetolerance test after overnight fasting is identical in control and OFr-fed rats".

In view of the above, one skilled in the art would have been dissuaded from utilizing such a composition in a method for treating hyperglycemic syndrome and/or type II diabetes in a subject as recited in the claimed invention (see independent claim 43).

The Supreme Court recently addressed the issue of obviousness in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007). While the KSR Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness inquiry, the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination. *KSR*, 127 S.Ct. at 1731.

Moreover, the Court indicated that there is "no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis." *Id.* As long as the test is not applied

as a "rigid and mandatory" formula, that test can provide "helpful insight" to an obviousness inquiry. *Id.*

Thus, as the publication does not provide "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does", applicants submit that ROBERFROID et al. fails to render obvious the claimed method.

ROBERFROID et al. describe food and pharmaceutical compositions comprising fructans, but ROBERFROID et al. do not describe compositions comprising oligosaccharides other than fructans. In this regard, it is believed that ROBERFROID et al. fail to render obvious the claimed compositions.

ROBERFROID et al certainly do not disclose or suggest the recited ingredients or amounts of claim 63. Indeed, there is no recognition by ROBERFROID of the amounts or ingredient recited therein. Moreover, a particular parameter or variable must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the parameter or variable might be characterized as routine or obvious. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). As the particular ingredients and amounts are not recognized as a result-effective variables by ROBERFROID et al, applicants submit

that ROBERFROID et al. fails to disclose or suggest the claimed invention.

Claims 22, 25-28, 35, 38, 39-42 were rejected under 35 USC 103(a) as allegedly being unpatentable over HIJI.

HIJI disclose that isomaltotriose can control or inhibit the increase of blood sugar (column 1, lines 15-34).

However, HIJI state (column 1, lines 37-41) that isomaltotriose is not "a desirable food additive" as it is absorbed through the intestinal tract. HIJI recommends at column 1, lines 49-53 to use a "non toxic, safe method" such as pullulan. In this regard, one skilled in the art would have been dissuaded from utilizing such a composition for a method for treating hyperglycemic syndrome and/or type II diabetes in a subject as recited in the claimed invention (see independent claim 43)

Applicants respectfully submit that independent 51 and 54 claims have been drafted to exclude the composition of HIJI. As to claim 63, HIJI do not disclose or suggest the recited ingredients or amounts. As a result, applicants respectfully submit that HIJI fail to render obvious the claimed composition.

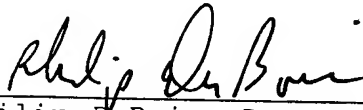
In view of the present amendment and foregoing Remarks, therefore, applicants believe that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Please charge the fee of \$210 for the extra independent claims added herewith, to our credit card set forth in the attached Credit Card Payment Form.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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